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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/685,297	10/10/2000	Robert B. Cody	3487-001146	4559

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EXAMINER
GORDON, BRIAN R

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/685,297	CODY, ROBERT B.	
	Examiner	Art Unit	
	Brian R. Gordon	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed June 30, 2003 have been fully considered but they are not persuasive. The 112, first paragraph, rejection is hereby maintained for reasons given herein. Applicant asserts that in MPEP 2164.02 it is recited that "The specification need not contain an example if the invention is other wise discloses in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation." The examiner hereby asserts that even one skilled in the art would find it difficult to understand how the invention is enable plus find difficulty in practicing the invention without a great amount of experimentation.

Applicant further states that the N specimens are "prepared by well know methods available to those of ordinary skill in the art." While applicant's asserts that preparation methods are well-known, the examiner asserts that the general act of preparing N specimens may encompass many actions or steps performed automatically by a device or manually by an individual. As previously recited in the previous office action, the specification and claims do not specifically describe or define what applicant intends for the preparation step to include. As such the statement is interpreted in the broadest scope which could be anything from collecting the samples, pouring the samples in containers, stirring or agitating the samples, and etc.

As to applicant's arguments as directed to the issue of homogenized fluids, it appears as if applicant intent is to state that the specimens are not homogenized fluids before being combined in the homogenizing volume. While this may be applicant's

intent the examiner asserts that a mixture may or may not be homogenized as such some samples containing different components may be considered a homogenized mixture.

As to the reactivity of chemicals applicant asserts "most chemicals do not react instantaneously or not at all." The examiner asserts that the time it takes for chemicals to react is dependent upon a number of factors including, the chemicals being combined, environmental factors (temperature, pressure, etc.), amount of each chemical, etc. Furthermore, there are no specific types of chemicals mentioned by applicant as to determine what would be the results in combining a number of unknown samples.

Chemicals are relatively unpredictable. Given a plurality of samples having unknown contents there is now way to predict reactions/interactions among the samples.

While it may be possible to determine a plurality of unknowns, applicants have not taught how to relate the unknowns to the original samples the unknowns came from. For example, if sample 1 contains unknowns A and B and sample 2 contains unknowns B and C, how would one relate analysis of unknowns to samples 1 and 2 to know that unknown B is in both?

What if unknowns are reactive with each other? There does not seem to be any provision for determination of an unknown reactant D in sample 3, which reacts wholly or partially with unknown reactant E in sample 4 to produce unknown product F which was not present in any sample, only the homogenized specimen.

Applicant asserts that in combining multiple samples for simultaneous analysis allows for a higher through put of samples. If that is the case, then why not combine N amount of the samples? What is the importance/significance of combining a lesser number of samples? If you can combine r samples with r being any integer less than N, then why not combine them all?

Applicant has provided a declaration that consists of a number of graphs that appear so show some type of results, however applicant has not provided sufficient a explanation of the graphs to understand what the results show and how the results are related to the instant specification.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The examiner has reviewed the specification and determined that it is unclear how the method of the invention may be employed. Applicant provides general antecedent basis for the method by reciting verbatim in the Summary of the Invention the steps of claim 1. The nature of the invention is understood to be a process of preparing a number of specimens and then taking a

lesser number of the specimens and mixing them together, after mixing, the specimens are then subjected to a type of analysis (mass spectroscopy) in which the mixed specimens are analyzed simultaneously. The results or data from the analysis of the mixture are then "deconvoluted" via a well known mathematical method, the Hadamard transform, in order to once again separate the data into its corresponding information relating to the individual specimens of the mixture. It is understood that the prior art discloses methods and devices for analyzing individual samples or specimens in which the samples and specimens contain individual elements, components, or molecules that are detected, analyzed, or identified by such methods as mass spectroscopy and deconvoluted by means such as the Hadamard transform (see McLafferty US 4,931,639).

Applicant's invention which requires the steps of a) preparing a plurality of N fluid specimens, b) introducing a first combination of r specimens wherein r is less than N into a homogenizing volume to create a homogenized specimens, c) introducing at least a portion of the homogenized specimen to the analyzing instrument and recording the results of the analysis maintaining an association with the combination of r specimens, d) introducing additional different combinations of specimens into said homogenizing volume and repeating steps b) and c) and e) with a programmed digital computer mathematically processing the recorded results to produce analysis corresponding to individual fluid specimens.

Applicant fails to provide an adequate amount of direction and specific working examples in which one would desire to use such a method. There are no specifics

given as to how the N specimens are "prepared." Furthermore, there is no reasoning given for "introducing a first combination of r specimens where r is less than N into a homogenizing volume".

There is also lack of basis of what is meant by "homogenizing" and the importance of conducting this step. The examiner considers an individual specimen, which contains different elements to be homogenized, and furthermore any mixture is a combination of uniformly distributed substances.

Applicant does not specify the type of specimens that are mixed so there is no guarantee that the samples will mix to form a homogeneous mixture. Depending the samples, it may be possible for the samples to be combined and produce a solid precipitate.

The discloser also lacks the proper evidence to determine that the method could be performed as claimed to allow one to obtain the results as claimed by applicant. The method suggests that two or more unknown samples are mixed together and then are subjected to analysis that allows one to identify characteristics of the individual samples. However, it is well known in the art that when chemicals are mixed together chemical reactions may occur in which a new chemical is produced or the original samples are altered or entirely consumed in the reaction. Since the originally prepared samples may be altered or consumed, it is unclear how one would analyze the mixed samples and then deconvolute the results to obtain data that would identify or relate to the original samples. This would be particularly difficult or incorrect if the original samples are consumed in the reaction. Since the mixing of the samples may provide for the

occurrence of unpredictable chemical reactions, it is unclear how such a method could be accurately executed as claimed by applicant. Therefore, the scope of the disclosure does not provide adequate support for enablement of the objective of the invention which appears to be in contrast of generally accepted scientific principles of mixing and analyzing chemicals.

Claim 2 recites that the specimens are gaseous specimens diluted with a carrier gas. The only mentioning of gas is found in the Background of the Invention on page 1, line 11 and Summary of the Invention on page 2, lines 27-28. However there is no working example given with which the specific method would be employed.

As recited above the prior art discloses the well known method of performing simultaneous mass spectroscopy analysis of samples, which may be injected into a system by means of electrospray nozzles (as given prior art see Background of Invention page 1, lines 6-10) that may be deconvoluted by means of the Hadamard transform and it is well known that a computer may be employed to perform this mathematical method. It appears that applicant has taken well known methods and principles (as admitted by applicant) to produce a method in which applicant now recites that multiple samples are combined. However due to the lack of working examples and evidence of how such a method would be beneficial the examiner hereby asserts that the specification is not enabled for the claimed method.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is (703) 305-0399. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

brg
September 5, 2003

Jill Warden
Supervisory Patent Examiner
Technology Center 1700